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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/333,680	11/03/94	WANG	CELL16

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EXAMINER
PRIEBE, S

ART UNIT
1632

PAPER NUMBER

DATE MAILED: 06/22/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/333,680

Applicant(s)
Wang et al.

Examiner
Scott D. Priebe, Ph.D.

Group Art Unit
1632



☒ Responsive to communication(s) filed on Mar 12, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 37-50, 52, 54, 56, and 57 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 40-45 is/are allowed.

☒ Claim(s) 37-39, 46-50, 52, 54, 56, and 57 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6,7+15

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

The amendment and response filed 3/12/98 is acknowledged. Claims 39, 41-44 and 48-50 have been amended. Claims 37-50, 52, 54, 56 and 57 are pending. The amendment indicated that claims 54 and 57 had been amended, but no amendment to these claims was provided. In future responses, applicant is requested to include only those claims which are amended, if it is desired to supply a clean copy of all pending claims, amended or not, this should be done as a clearly indicated appendix.

Specification

The abstract of the disclosure is objected to because it is not commensurate in scope with the claimed invention. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The Wang declaration under 37 CFR 1.132 filed 3/12/98 is sufficient to overcome the rejection of claims 46, 48, 49, 54, 56 and 57 based upon a lack of enablement. The rejection of claims 46, 48, 49, 54, 56 and 57 under 35 USC 112, first paragraph is withdrawn.

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Claims 48 and 49 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Claims failing to recite an element critical or essential to the practice of the claimed invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claims recite that the cells are able to support growth of an adenovirus that is missing essential genes of the E1, E2A, and/or E4 regions, but the structural elements recited in the claim are limited to expression cassettes that encode essential E1 and E4 products. The E2A region is essential for growth of an E2A-deficient adenovirus, and unless the cell expresses the E2A genes, the cell would be unable to support replication of an E2A-deficient adenovirus. The claims should be amended to recite that the cell also comprises the adenoviral E2A region under control of an inducible promoter, as taught at page 14, lines 9-17 of the specification.

Claims 37-39, 46-50, 52, 54, 56 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites the limitation "the adenoviral genome" in line 2; and claim 38 recites the limitation "the virus" in line 2. There is insufficient antecedent basis for these limitations in the claims. The following is suggested in place of "the adenoviral genome" and "the virus"; --the genome of said adenovirus--. In the case of claim 38, it is the adenoviral genome that comprises the deletions, not the virus itself.

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Claims 37, 38, 46, 47 and 50 recite that the genome "a transgene that replaces any one of said deletions", which makes no sense, if it has a deletion, the deletion cannot be replaced. The claim should recite that the transgene is inserted in place of the deleted adenoviral sequences. In addition, it is unclear if the transgene is present, and if so where, when the genome comprises two lethal mutations that are not deletions.

Claims 46, 48 and 49 recite "deletion ... or mutation selected from the group consisting of E1, E2A, E4 early gene regions, viral structural genes," which makes little or no sense and is grammatically incorrect. It is especially unclear what "viral structural genes," is supposed to convey. The E1, E2A and E4 regions are not deletions or mutations. The claims should simply recite that the vector comprises --a lethal deletion or mutation in two early gene regions selected from the group consisting of the E1, E2A or E4 early gene regions of said adenoviral vector--.

In claims 39 and 47 it is unclear whether "at least two lethal deletions" are present in each of the E1 and E4 regions, i.e. four deletions in all, or each of the E1 and E4 regions comprises a one of the two lethal deletions. If the latter, it is suggested that the claim recite --comprising a lethal deletion in each of the E1 and E4 early gene regions of said adenoviral vector--. Also, "the E1 and E4 early gene regions" lacks antecedent basis.

Claim 50 recites "at least two lethal deletions selected from the group consisting of E1 and E4 early gene regions" which makes little or no sense and is grammatically incorrect. The E1 and E4 regions are not deletions or mutations. The claims should simply recite that the vector

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comprises -- a lethal deletion in each of the E1 and E4 early gene regions of said adenoviral vector--.

Claims 52, 54, 56 and 57 are indefinite as indicated above through their dependence upon one of claims 38 or 46-50.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 37, 38, 46, 47, 52, 54, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Gregory et al., US 5,670,488.

Gregory et al. discloses PAV vectors and adenovirus which in which the only adenoviral sequences present are the ITRs and packaging sequence and a transgene in place of the deleted E1, E2A, E3 and E4 regions (including E4 ORFs 3 & 6) *inter alia*. See Gregory et al. Fig. 16A & 16B; col. 12. lines 7-50; col. 43, line 5 to col. 44, line 34.

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Allowable Subject Matter

Claims 40-45 are allowed.

Claims 39 and 50 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, Ph.D., can be reached on (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SDP

Scott D. Priebe, Ph.D.
Patent Examiner
Art Unit 1632

June 19, 1998

Jasmine C. Chambers
JASEMINE C. CHAMBERS, PH.D.
SUPERVISORY PATENT EXAMINER
GROUP 1800-1600